



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,898	01/07/2002	Douglas A. Luehmann	S0002-US02	4305

24994 7590 07/08/2003

GAMBRO, INC
PATENT DEPARTMENT
10810 W COLLINS AVE
LAKEWOOD, CO 80215

EXAMINER

DRODGE, JOSEPH W

ART UNIT

PAPER NUMBER

1723

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,898

Applicant(s)

LUEHMANN ET AL

Examiner

JOSEPH DRODGE

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

Art Unit: 1723

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 112

1. Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 6-8, it is unclear whether “feedback loop” recites means for monitoring and controlling a fluid characteristic of the system or alternatively, a flow loop to recirculate fluids. Since the instant Specification more thoroughly described flow recirculation, “feedback loop” was interpreted as a limitation concerning means for recirculating fluids from the sub-system supply line to anywhere upstream of such line.

Claim Rejections - 35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Art Unit: 1723

3. Claims 1, 2, 5, 6, 8, 11, 12, 15-20, 23 and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Peterson et al patent 6,228,255.

Peterson et al 255 discloses with regard to independent claims 1, 15 and 26, as summarized in figure 2, tanks 1 and 2 (functioning to collect and store water as it is filtered), inlet line 10, outlet lines 109 and 130, pump 128, sub-system supply line 138, branch connections 130 and demand devices 110 (of relatively “high” demand when in use, if necessary “high” or “low” demand are relative terms).

Concerning independent claim 15, also see main inlet lines 101, water processing/purification units 88 and 90 [as in claim 16], plural main branch connections including connections to bypass or be routed through booster pump 84, main outlet line 107 and additional main branch connections including connections to ports 89 and 91 for sampling.

Concerning various dependent claims: for claim 17, see carbon tank 1 with carbon tank 2 being considered the storage tank of the supply sub-system; for claims 2, 12, 18-20, 23, 27 and 28, there are a plurality of using dialysis devices 110 which are of relatively high or low demand depending upon frequency and duration of use, etc. and which constitute “medical devices”; for claim 5, the dialysis devices receive dialysis fluid simultaneously when more than one patient is being treated by a device 110; for claims 6 and 8, feedback loop from tank 124 to pump 128 is upstream of the branch connection and for claim 11 see ultrafilter 118.

4. Claims 1, 2, 5-8, 11-18 and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Faylor et al patent 3,870,033.

Art Unit: 1723

As to independent claims 1, 15, and 26, Faylor et al disclose storage tank 24, inlet line from a supply system between cartridge filter 58 and the tank 24, outlet line 26, pump 84, subsystem supply line 82 etc., and “high” or “low” demand devices 144 served by branch connections 142. Regarding claim 15 and also claim 16, also disclosed are numerous water purifying and processing devices in series, (40, 42, 45-48, etc.), branch lines 32a and 32b, main inlet line 30, and a main outlet line leading through cation and anion exchangers 52 and 54 and mixed bed device 56. If necessary, municipal water input line 30 can be considered to be one of many main branch connections routed from a main outlet line of the water distribution network from the water treatment and processing plant of any community having the system of Faylor et al.

Concerning various dependent claims: for claims 2, 12-14, 18, 23-25 and 27, see column 1, lines 5-9 and 33-37, etc. concerning end use devices as comprising semiconductor manufacturing, pharmaceutical manufacturing and medical facilities; for claim 11, see ultrafilter 90, for claim 5, see plural use devices being simultaneously in operation in column 9, lines 8-11, for claims 6-8 see feedback loops 160-26 and 146-148-151 which are both upstream and downstream of the branch connections and for claim 17, see additional water storage tank 148.

Art Unit: 1723

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1723

7. Claims 3, 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al patent 6,228,255 in view of Peterson et al patent 6,231,199.

Claims 3, 21 and 29, require devices to include dialyzer re-use machines. Patent 199 teaches such machines in column 7, lines 59-60 and column 8, lines 24-30 alongside regular dialysis machines. At the time the present invention was made, it would have been obvious to one of ordinary skill in this art to service more patients with more diverse dialysis needs.

8. Claims 4, 22 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al patent 6,228,255 in view of Peterson et al patent 6,235,199 as applied to claims 1, 15 and 26 above, and further in view of Gortz et al patent 4,332,264.

These claims differ in requiring the devices to constitute dialyzer pre-cleaning units. Gortz et al teach such dialyzer reuse devices and pre-cleaning being performed before each use in column 2, lines 24-33 and 44-54, etc. At the time the present invention was made, it would have been obvious to one of ordinary skill in this art to have coupled the 255 system/method modified by 199 to include reuse dialyzers, to have coupled such reuse devices to pre-cleaning devices, as suggested by Gortz et al, to insure the health, safety and effectiveness of the dialyzing equipment.

9. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al patent 6,228,255 in view of Kenley et al patent 5,283,072.

Claims 9 and 10 differ in requiring the tank to have a spray head that is connected to the tank inlet and also to the feedback loop. Kenley et al teach such spray head 205 for a tank 205 that receives

Art Unit: 1723

a variety of process fluids and chemicals in column 13, line 66-column 14, line 16. At the time the present invention was made, it would have been obvious to one of ordinary skill in this art to have modified the system of 255 to include such spray heads for the storage tanks, as suggested by Kenley et al, in order to promote dispersion and dissolution of chemicals in the tank to constitute dialyzing solutions of maximum effectiveness for the dialyzers.

10. Claims 13, 14, 24, 25, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al patent 6,228,255 in view of Peterson et al patent 6,235,197.

Claims 13, 14, 24 and 25 differ from '255 in requiring substitution of semiconductor or pharmaceutical manufacturing devices for the dialysis devices. Patent 197 teaches such end use devices in column 13, lines 11-22. At the time the present invention was made, it would have been obvious to one of ordinary skill in this art to have utilized the system of 255 to service such manufacturing devices, as suggested by 197, since these devices also require a reliable, and compact plumbing system and highly purified, sterilized fluids.

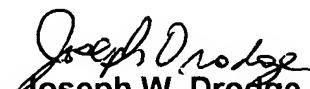
Claims 31 and 32 differ in requiring the steps of disinfecting and isolating the subsystem to treat with heat or disinfecting chemical , respectively. Patent 197 teaches such disinfecting and isolating in column 3, lines 8-10 and column 8, lines 32-64. At the time the present invention was made, it would have been obvious to one of ordinary skill in this art to have modified the process of 255 by providing means for such disinfecting and isolating and then performing such method steps, as taught by 197, in order to ensure the safety of patients being treated by the dialyzers.

Art Unit: 1723

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph W. Drodge whose telephone number is (703) 308-0403. The examiner can normally be reached on Monday-Friday from approximately 8:30 AM - 4:45 PM.

The fax phone number for this Group is (703) 872-9310 or (703) 872-9311 for after final submissions. When filing a FAX in Tech Center 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communication with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.


Joseph W. Drodge
Primary Examiner
Art Unit 1723

JWD
July 3, 2003